UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,796	06/11/2001	Patricia De Jong	B0-42260	9646

466 7590 06/19/2003

YOUNG & THOMPSON
745 SOUTH 23RD STREET 2ND FLOOR
ARLINGTON, VA 22202

EXAMINER
HENDRICKS, KEITH D

ART UNIT	PAPER NUMBER
1761	12

DATE MAILED: 06/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/857,796	DE JONG ET AL.	
	Examiner	Art Unit	
	Keith Hendricks	1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

i) The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amendment of the claims to include the limitations of either or both of "40-80 weight % oligosaccharides...", and "the amount of the at least one yeast strain being 0.5-5 g", is not sufficiently described in the specification in such a way as to reasonably convey to one skilled in the art that applicants actually had possession of a composition with either of these limitations. The clarity of these two passages was questioned and discussed during the interview of March 27, 2003.

Claims 27, 41 and 55 are not properly supported by the specification. The limitations of "a total nutrition and a clinical nutrition" do not correspond, within the teachings of the specification, to the recited percentages of "40-80 weight % oligosaccharides...". See pages 5-6 of the specification, where the only description of this percentage is for that of a "supplement", specifically (pg. 5). Note that a true direct translation of the disclosure in the Dutch priority paper refers to this as a "feeding supplement". Regardless, the recited values at the top of page 6 of the specification, with regard to a "total nutrition", do *not* correspond to that previously described as a "supplement" on page 5. Thus, applicant is not entitled to a claim broadly utilizing these percentages for any such random composition, including "a total nutrition and a clinical nutrition."

It is noted that at page 3, lines 16-17 of the specification, it is stated that "In general the oligosaccharides will make up 5 wt% to 50 wt% of the total preparation." The inconsistent use of the terms "preparation", "total preparation", "probiotics", "concentration of probiotics", and various "supplements", renders the teachings of the specification unclear, and leads to uncertainty with regard to the true composition described at page 5, lines 23-28 of the specification. One skilled in the art, upon reading the specification as a whole, may arrive at the conclusion that the "supplement" described at this

passage, is made of the probiotic "preparation", which is described throughout the specification as containing *both* the probiotic microorganisms *and* the oligosaccharides. Clarification with respect to the scope of the claimed invention, is requested.

Further, claims 38 and 52 appear to conflict with base claims 28 and 42, and with the teachings of the specification as well. Claims 28 and 42 provide for "the amount of the at least one yeast strain being 0.5-5 g", while claims 38 and 52 state that the compositions "further comprise dead yeast cells." Applicants' arguments at pages 9-10 of the response have been considered but are not deemed persuasive. Applicants' "reasoning" does not find direct support within the teachings and spirit of the originally-filed specification, at page 4 or elsewhere. In fact, the teachings at this passage of the specification are such that one skilled in the art may just as easily interpret, or "reason", from the statement "if dead *Saccharomyces cerevisiae* is also used, this is administered in a quantity of 0.5 to 5g per day", that this amount would still apply to the entire administered quantity, i.e. the "total concentration of the probiotics" recited in the paragraph directly above this statement. In other words, it would reasonably appear that the statement would continue to refer to the total amount of probiotics, including both bacteria and *Saccharomyces cerevisiae*. Similarly, the phrase does *not* provide support for a composition containing a total of 0.5 to 5g of yeast, as applicants claim. It provides for the administration of a total quantity of 0.5 to 5g of yeast over the entire course of a day. This is a suggested daily dosage, and in no way provides for a composition comprising the recited amounts. Thus, the scope and enablement of the current claims is in question. Applicants have provided no clear and definite nexus to the conclusion at which they arrived, and may not simply choose one interpretation at this juncture in order to circumvent a prior reference. Applicants are entitled to be their own lexicographers, *if* such action is made clear from the teachings of the original specification. However, this is not the case with the newly-added claim language.

It is also noted that applicants' claims 28-55 are not commensurate in scope with the teachings of the specification. The statement at page 4, that "if dead *Saccharomyces cerevisiae* is also used, this is administered in a quantity of 0.5 to 5g per day", do not provide for the general use of any random yeast in this amount. Applicants' claims 28-55 recite "at least one yeast strain". However, *Saccharomyces cerevisiae* is but one of thousands of types of yeasts. The specification provides a statement for the administration of *Saccharomyces cerevisiae* in a total quantity of 0.5 to 5g over the entire course of a day. It does not provide a breakdown of how much this would translate to per feeding, or per any other dosage unit of measure.

ii) The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27, 41 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding the recited " total nutrition" and "clinical nutrition" in claims 27, 41 and 55, it is unclear as to what is encompassed by these terms. Further, the delineation and distinction between the two is not set forth, and would not be readily apparent to one skilled in the art.

** *Accordingly, due to the rejections under* 35 U.S.C. 112 *above, the prior art rejections provided previously on the record, will be maintained below for all pending claims, until such time as the record may be clarified such that one skilled in the art may more readily and accurately determine the enabled scope of the claimed invention.*

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

i) Claims 14-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al. (WO 97/34615).

Brown discloses the production of a probiotic composition. The composition comprises oligosaccharides, and microorganisms such as *Saccharomyces* yeast, and *Bifidobacterium* or *Lactobacillus* bacteria, or combinations thereof (pg. 3, and claim 2). "Typical concentration of microorganisms administered is 10^3 to 10^{13} cells per day. Usually, about 10^8 cells per day are used in probiotic administration." Suitable oligosaccharides are listed at page 3, and include fructo- and galacto-oligosaccharides, as well as those from soybean. These meet the limitations of instant claims 15-22. Weights and percentages of the oligosaccharides within the composition are provided at pages 3-4, as well as in the examples and reference claims 6-7, thus within the ranges of instant claim 25. It is noted that a portion of the *Saccharomyces* yeast added to the medium would naturally, eventually be dead, thus meeting the limitation of instant claim 24. Finally, as all of the starting materials utilized in the making of the composition are in dry form, the end composition would be expected to meet the "dried form" limitation of the instant claims.

ii) Claims 14-55 are rejected under 35 U.S.C. 102(e) as being anticipated by Cavadini et al. (US 5,968,569).

Cavadini et al. discloses the production of a dried pet food or cereal product containing probiotics. The product is formulated to contain s 10^6 to 10^{12} cells of the probiotics (top col. 7). "The probiotic microorganism may be selected from one or more microorganisms suitable for human or animal consumption (bottom col. 2), and include yeast such as *Saccharomyces*, and *Bifidobacterium* or *Lactobacillus* bacteria (top col. 3). Various types of soluble or insoluble fiber are provided, including various bran sources such as oats, wheat, and soy oligosaccharides, as well as inulin and fructooligosaccharides (col. 3-4). These meet the limitations of instant claims 15-22. The preferred amounts of fiber in the preparation are from 1-20%. It is noted that a portion of the *Saccharomyces* yeast added to the medium would naturally, eventually be dead.

iii) Claims 14-55 are rejected under 35 U.S.C. 102(e) as being anticipated by Masuyama et al. (US PAT 6,284,243).

Masuyama et al. provide a "physiologically functional food" comprising lactic acid bacteria with a fermented milk product, or alternatively, a "lactic acid bacterium and yeast co-fermented milk" (col. 2, line 50). The bacteria include strains from *Lactobacillus* and *Bifidobacterium*, and the recited yeast

include *Saccharomyces*. The culturing is terminated "when a cell density reaches at least 10^7 cells/ml". Upon fermentation, "the used cells may remain intact", or the fermented product may be sterilized (col. 3). The composition may be concentrated and dried, or made into a powder, and "a filler such as dextrin may be added to the milk in order to facilitate formation of the powder" (col. 3, lines 48-55). The physiologically functional food may also "contain additives, such as saccharides, proteins," etc. Various saccharides are provided at column 3, including "glucose, sucrose, oligosaccharides such as raffinose and stachyose". The oligosaccharides raffinose and stachyose are known in the art to be derived from soy. The active ingredient (i.e. the fermented milk, containing the microorganisms) may be blended in any amount with the additives or auxiliary agents, "but it is preferably from 5 to 100 w/w%" (top col. 4). Specific amounts of the components are provided in the examples. In example 2, a fermented milk powder composition was mixed with a test feed, which comprised the fermented powder in an amount of 10%, soybean protein at 16%, cellulose at 5%,and starch (as α-starch:sucrose = 2:1) at 66%. Finally, the entire physiologically functional food may be formulated as a beverage, food product, tablet, capsule or granule. It is noted that a portion of the *Saccharomyces* yeast added to the medium would naturally, eventually be dead.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (703) 308-2959. The examiner can normally be reached on M-F (8:30am-6pm); First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (703) 308-3959. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9565 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

KEITH HENDRICKS
PRIMARY EXAMINER